Summary of the
Program Policy and Structure Committee Teleconference
October 23, 1996

The Policy and Program Structure Committee of the National Environmental Laboratory Accreditation Conference (NELAC) convened by teleconference on October 23, 1996, at 1 pm. The committee meeting was led by its chair, Dr. Kenneth Jackson of the NY State Department of Health. *The purpose of this meeting was to continue discussing revisions proposed for Sections 1.8 and 1.9 of Chapter 1 of the standards.* A list of action items is provided in Attachment A. A list of participants is given in Attachment B. Materials distributed to the committee included:

- Agenda (Attachment C)
- Sections 1.9 (Scope of NELAC) and 1.10 (Organization of the Accreditation Requirements) revised to reflect recent committee discussions (Attachment D)
- Section 1.6.2.3 - draft wording on accrediting authorities (Attachment E).

GENERAL ISSUES

Dr. Jackson stated that the *ad hoc* Coordination Committee is developing the glossary for the completed constitution, bylaws, and standards with Dr. Fred Haeberer's leadership. Ms. Marlene Moore volunteered to be the liaison from this committee and will assist using an electronic copy of the current working text of Chapter 1.

1.6.2.3 ACCREDITING AUTHORITIES

The draft wording discussed here is given in Attachment D: new wording is given in italics. This draft wording is intended to clearly delineate the roles and responsibilities of NELAC accrediting authorities. Following discussion, it was agreed to reword paragraph one, item b, to read:

> "b) any State *which requires laboratory testing in conformance with* at least one of the EPA program listed within the scope of NELAC (see Section 1.9)"

Paragraph two was reworded, omitting the last sentence:

> "A primary accrediting authority is *one* which ensures directly that the laboratory is in conformance with the NELAC standards. A secondary accrediting authority is *one* which, through reciprocity, recognizes the *accreditation* activities of a primary accrediting authority."

1.6.2.3.3 Responsibilities of primary accrediting authorities

The first paragraph was changed as follows:

> "Once a State or federal agency has been approved by NELAP as being an entity whose accreditation and assessment program meets all of the requirements of NELAC, it will be a primary accrediting authority, and it (the accrediting authority) will have full responsibility for..."

The second paragraph, first sentence, was changed as follows:

> "A State accrediting authority *is* the primary accrediting authority for all NELAC accredited laboratories in that State."

In addition, the last 11 lines of the paragraph, beginning "For example, ..." were deleted.

The third paragraph, first sentence, was changed as follows:

> "In addition, a(n) primary accrediting authority may contract *assessment* activities to a third party [non-government] body (assessor body)."

1.6.2.3.4 Responsibilities of secondary accrediting authorities
Wording in this section was changed as follows:

> "A secondary accrediting authority must be approved by NELAP as being an entity whose accreditation and assessment program meets all of the requirements of NELAC."

> "A secondary accrediting authority may require laboratories to submit an application and will retain the legal authority for enforcement of all applicable laws and rules relating to the accreditation of laboratories under its jurisdiction. However, it must recognize through reciprocity, and must not replicate, any of the *assessment* functions of a primary accrediting authority."

RECIPROCITY

The issue of reciprocity was discussed. Ms. Pauline Bouchard volunteered to distribute draft wording, based on earlier work of this committee.

SMALL LABORATORY ISSUE

The need for addressing the issues specific to small laboratories in this policy chapter was raised. While each of the standing committees is expected to address those needs in relation to its chapter of the standards, Chapter 1 should address several more general issues. After discussion, it was agreed that five issues should be addressed: 1) quality assurance/quality control (QA/QC) personnel, 2) credentials, 3) frequency of analysis of performance evaluation (PE) samples, 4) process documentation, and 5) QC sample frequency. Mr. Robert Luna and Mr. Tom McAninch agreed to draft appropriate wording for discussion at the next meeting of this committee.

NEXT TELECONFERENCE

The next scheduled teleconference of this committee is Wednesday, November 6, at 1 pm Eastern Standard Time (EST) to complete this discussion of Chapter 1, to address the action items (Attachment A), and to address comments from the *ad hoc* Coordination Committee. Additional teleconferences are scheduled for November 20, December 4, and December 18, 1996, and January 8 and 22, 1997; all are planned to begin at 1 pm.

Attachment A

ACTION ITEMS
Policy and Program Structure Committee Teleconference
October 23, 1996

ACTION	Date Completed
Pauline Bouchard will draft wording on the opening paragraph for this chapter for the next meeting.	
Pauline Bouchard will distribute a copy of the May 1996 wording on reciprocity to the committee for discussion at the next meeting.	
Robert Luna and **Tom McAninch** will draft wording to address "small labs" for discussion at the next meeting.	

Attachment B

LIST OF PARTICIPANTS
Policy and Program Structure Committee Teleconference
October 23, 1996

Name	Affiliation	Phone Numbers
Ken Jackson, Chair	NY State Department of Health	T: 518/485-5570 F: 518/485-5568
Pauline Bouchard	MN Department of Health	T: 612/623-5331 F: 612/623-5514
Marcia Davies	US Army, Corps of Engineers	T: 402/697-2555 F: 402/697-2595
Robert Luna	City of Longmont, CO	T: 303/651-8666 F: 303/682-9543
Tom McAninch	Eastman Chemical Co.	T: 903/237-5473 F: 903/237-6395
Marlene Moore	Advanced Systems, Inc.	T: 302/834-9796 F: 302/995-1086
Gene Tatsch, Support Contractor	Research Triangle Institute	T: 919/541-6930 F: 919/541-7386

Attachment C

AGENDA
Policy and Program Structure Committee Teleconference
October 23, 1996

1. Attached is the final (?) version of the sections on "Scope of NELAC" and "Organization of the Accreditation Requirements", which we completed during our most recent teleconference. These are now numbered 1.9 and 1.10 respectively. Please insert them in the newest version of Chapter 1 (which I circulated a coupled of weeks ago) on page 14 (1.9 Scope of NELAC). The remaining sections of Chapter 1 will then have to be renumbered when we deal with them.

2. The schedule of future teleconferences has been amended as follows:

   Oct. 23, Nov. 6, Nov. 20, Dec. 4, Dec. 18, Jan. 8, and Jan. 22.

   All will be from 1:00 - 3:00 Eastern Standard Time.

3. In preparation for the Oct. 23 teleconference, please do the following:

   a) Read Chapter 1 and think about the wording of the introduction. What changes do we need to make to reflect the changes we have made in the chapter?

   b) Think about "issues" we need to address and incorporate into Chapter 1; e.g., what we should say about the "National Database." Others?

   c) Consider what we need to do to make sure the special needs of small laboratories are addressed in the chapter (Robert and Tom agreed to think about this).

1.9 SCOPE OF NELAC

The scope of NELAC shall encompass the necessary scientific testing to serve the needs of the States, United States Environmental Protection Agency (EPA), and other Federal agencies involved in the generation and use of environmental data, where such generation or use is mandated by USEPA statutes and pursuant regulations. A laboratory is encouraged to use the NELAC standards for all other tests.

Applicable USEPA statutes include the Clean Air Act (CAA); the Comprehensive Environmental Response Compensation and Liability Act (CERCLA); the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); the Federal Water Pollution Control Act (Clean Water Act; CWA); the Resource Conservation and Recovery Act (RCRA); the Safe Drinking Water Act (SDWA); and the Toxic Substances Control Act (TSCA). The standards shall also include provisions to permit special requirements or fields of testing promulgated by any of the accrediting authorities.

The standards shall not be implemented or administered in a way which limits the ability of local, state or federal agencies to investigate and prosecute enforcement cases. Specifically, when engaged in the collection and analysis of forensic evidence to support litigation, those agencies may use any procedure that is appropriate given the nature of the investigation, subject only to the bounds of sound scientific practice. The standards shall not apply to governmental laboratories engaged solely in the analysis of forensic evidence.

1.10 ORGANIZATION OF THE ACCREDITATION REQUIREMENTS

1.10.1 Overview

The accreditation requirements shall be based on fields of testing, using the tiered approach shown in Figure 1-3. Accreditation will be granted for the use of specified approved methods, and on an individual analyte basis; e.g., a laboratory determining lead by both inductively-coupled plasma mass spectrometry (USEPA Method 200.8) and graphite furnace atomic absorption spectrometry (USEPA Method 200.9) would require accreditation for lead method 200.8 and lead by method 200.9. Loss of accreditation for an analyte would not automatically result in loss of all other analytes accredited under the method, provided the laboratory remained proficient in the determination of the other analytes.

Using the tiered approach, a laboratory must meet the basic requirements and those additional specific tiers of requirements that are linked to the basic requirement for a particular test or activity. For example, a laboratory seeking accreditation in hazardous waste organic testing under the auspices of RCRA must meet all the requirements listed in general laboratory (NELAC Chapter 5), chemistry (NELAC Chapter 5, Appendix D.1), RCRA regulations (40CFR261), and the method(s) used (SW846 5030/8240). In some RCRA and other USEPA programs, the regulations mandate the method to be followed for reporting data, and for some waste testing the RCRA SW846 methods are considered guidance. In the above example, an accredited laboratory

is required to conform with the NELAC Chapter 5, Appendix D.1, and method-specific criteria. The laboratory must be familiar with the RCRA requirements and, it the test method is mandated, the specific regulatory RCRA program criteria must be followed.

The field of testing structure provides flexibility by allowing for the incorporation of new methods or new instrumentation without the applicants repeatedly demonstrating the basic requirements. This scheme eliminates redundancy, and structures appropriate and specific accreditation requirements to meet the needs of environmental laws and regulations. Regulators are thus provided with environmental sample testing results generated by laboratories according to specified or demonstrably equivalent methods and quality assurance protocols. Additionally, the adoption of method-specific, analyte and supplemental classifications allows for the design of accreditation to suite needs of individual laboratories and accrediting authorities. This flexibility shall promote reciprocity among all the participating accrediting authorities. The field of testing approach proposed shall also allow for the future incorporation of performance based measurement systems (PBMS) by substituting an approved PBMS for the specified analytical methods.

In addition, a category of supplemental accreditation is designated for additional methods or analytes required by an accrediting authority. Supplemental accreditation shall be reserved for methods or analytes that are not required under any of the USEPA programs that are part of NELAC, and it shall not be used to modify any NELAC standards for analytes or methods. Any supplemental requirements essential to meet the specific needs of an accrediting authority would be added at the method-specific or analyte level, and must be approved by NELAC.

1.10.2 General Laboratory Requirements

The general requirement are applicable to all laboratory applicants regardless of their size, volume of business, or field of testing. The organizational structure, or procedures used by applicant laboratory organizations to meet these general requirements may differ as a function of size or scope of testing of an organization. The general requirements shall include all the elements outlined in General Requirements for the Competence of Calibration and Testing Laboratories, ISO/IEC Guide 25: 1990 (E). It is the laboratory's responsibility to conform with the relevant health and safety and environmental compliance requirements. Accreditation under NELAC should not be considered to be a judgment that the laboratory is in compliance with any other environmental control or occupational health statute or regulation, either Federal or State.

The following applicable requirements are presented in Chapter 5 (Quality Systems): Organization and Management (5.4); Quality System - Establishment, Audits, Essential Quality Controls and Data Verification (5.5); Personnel (5.6); Physical Facilities - Accommodation and Environment (5.7); Equipment and Reference Materials (5.8); Measurement Traceability and Calibration (5.9); Test Methods and Standard Operating Procedures (5.10); Sample Handling, Sample Acceptance Policy and Sample Receipt (5.11); Records (5.12); Laboratory Report Format and Contents (5.13); Subcontracting Analytical Samples (5.14); Outside Support Services and Supplies (5.15.); and Complaints (5.16).

1.10.3 General Field Sampling Requirements

(To be developed)

1.10.4 Chemistry Requirements

The following applicable requirements are presented in Section D.1 of Appendix D of Chapter 5 (Quality Systems): Positive and Negative Controls (D.1.1); Variability and/or Reproducibility (D.1.2); Accuracy (D.1.3); Test Sensitivity (D.1.4); Selection of Appropriate Statistical Analysis Methods (D.1.5); Selection and Use of Reagents and Standards (D.1.6); Selectivity (D.1.7); and Constant and Consistent Test Conditions (D.1.8).

1.10.5 Whole Effluent Toxicity Requirements

The following applicable requirement are presented in Section D.2 of Appendix D of Chapter 5 (Quality Systems): Positive and Negative (D.2.1); Variability and/or Reproducibility (D.2.2); Accuracy (D.2.3); Test Sensitivity (D.2.4); Selection of Appropriate Statistical Analysis Methods (D.2.5); Selection and Use of Reagents and Standards (D.2.6); Selectivity (D.2.7); and Constant and Consistent Test Conditions (D.2.8).

1.10.6 Microbiology Requirements

The following applicable requirement are presented in Section D.3 of Appendix D of Chapter 5 (Quality Systems): Positive and Negative (D.3.1); Variability and/or Reproducibility (D.3.2); Accuracy (D.3.3); Test Sensitivity (D.3.4); Selection of Appropriate Statistical Analysis Methods (D.3.5); Selection and Use of Reagents and Standards (D.3.6); Selectivity (D.3.7); and Constant and Consistent Test Conditions (D.3.8).

1.10.7 Radiochemistry Requirements

(To be developed)

1.10.8 Field Measurement Requirements

(To be developed)

1.10.9 USEPA Program and Method Requirements

Laboratories must meet all relevant USEPA program requirements, including quality assurance/quality control (QA/QC), use of specified methods, and other criteria.

Attachment E

DISCUSSION TEXT

1.6.2.3 Accrediting Authorities

An accrediting authority can be either a) any federal agency with responsibility for operating mandated environmental programs which require laboratory testing, or b) any State.

1.6.2.3.1 Fair Representation of Accrediting Authorities

The accrediting authorities must have a fair and representative voice in the National Environmental Laboratory Accreditation Conference. NELAC shall establish the basic scope, structure, and standards of the national program. Acceptance of the national performance standards, in lieu of state standards, shall be significantly enhanced by fair and meaningful participation of state accrediting authorities in the establishment of the national program and standards that are forthcoming from that program.

1.6.2.3.2 Application to Serve as an Accrediting Authority

To be recognized under NELAP, each State of federal agency, when applying for approval as an accrediting authority, must within three years: a) have adopted the necessary minimum standards and procedures prescribed by NELAC; b) have trained its assessors according to the NELAC procedures; and c) have undergone an evaluation by the EPA oversight office (NELAP).

A State must also specify the agency within the State that will function as the accrediting authority in that State, and demonstrate to USEPA that it has the necessary legal and regulatory authority conferred upon it by State law to operate the program, including enforcement of all relevant standards. A federal agency must indicate which program within the agency will be the accrediting authority for the agency.

Failure in any of these areas would preclude a federal agency or Sate from being recognized under NELAP.

1.6.3.3.3 Responsibilities of Accrediting Authorities

Once a State of federal agency has been approved by the EPA oversight office (NELAP) as being an entity whose accreditation and assessment program meets all of the requirements of NELAC, the accrediting authority will have full responsibility for:

(a) Using the NELAC standards as the basis for assessing the qualifications of laboratories applying for or wishing to retain NELAC accreditation;

(b) Ensuring conformance by the laboratories it accredits with the national standards established by NELAC:

(c) Accrediting applicant laboratory organizations through the review and approval of

applications, performance of on-site assessments, evaluation of results on proficiency testing samples, and enforcement of all applicable laws and rules relating to accreditation; and

(d) Submitting the names and appropriate accreditation material to the EPA for inclusion in the national laboratory database.

In addition, an accrediting authority may contract accreditation activities to a third party (non-government) body (assessor body). If any of these activities are contracted to a third party, the accrediting authority retains responsibility for ensuring compliance with the standards established by NELAC. If a State chooses not to participate in all or part of the NELAC program, laboratories in that State may obtain accreditation for those areas not covered by the accreditation program of that State from a participating State or federal agency that is approved under NELAP.

1.6.2.3.4 Accreditation Fees

Accrediting authorities may adopt and impose laboratory accreditation fees which reflect their costs to maintain the accreditation program.